

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

LEO PHARMA A/S, LEO
LABORATORIES LIMITED, AND LEO
PHARMA, INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES UT, INC.,
AND ACTAVIS, INC.,

Defendants.

C.A. No. 16-333-SLR

LEO PHARMA A/S, LEO
LABORATORIES LIMITED, AND LEO
PHARMA, INC.,

Plaintiffs,

v.

PERRIGO UK FINCO LIMITED
PARTNERSHIP AND PERRIGO
COMPANY,

Defendants.

C.A. No. 16-430-SLR

**DECLARATION OF JUSTIN A. MACLEAN IN SUPPORT OF
DEFENDANTS' ANSWERING BRIEF ON CLAIM CONSTRUCTION**

I, Justin A. MacLean, hereby declare as follows:

1. I am an attorney at law duly licensed to practice law in the State of New York, *pro hac vice* to the United States District Court, District of Delaware, and am a Shareholder for the law firm of Greenberg Traurig, LLP, attorneys of record for Defendant Actavis Laboratories UT, Inc. ("Actavis") (collectively referred to, with Perrigo UK Finco Limited Partnership and

Perrigo Company (“Perrigo”), as “Defendants”) in the above entitled action, and make this declaration in support of Defendants’ Answering Claim Construction Brief. Unless otherwise stated, I have personal knowledge of the facts set forth in this declaration, and if called as a witness, could and would competently testify as set forth below.

2. Attached hereto as Exhibit 1 is a true and correct copy of U.S. Patent No. 6,787,161.

3. Attached hereto as Exhibit 2 is a true and correct copy of U.S. Patent No. 6,844,013.

4. Attached hereto as Exhibit 3 is a true and correct copy of U.S. Patent No. 7,410,656.

5. Attached hereto as Exhibit 4 is a true and correct copy of U.S. Patent No. 8,278,292.

6. Attached hereto as Exhibit 5 is a true and correct copy of U.S. Patent No. 8,372,827.

7. Attached hereto as Exhibit 6 is a true and correct copy of U.S. Patent No. 8,372,828.

8. Attached hereto as Exhibit 7 is a true and correct copy of U.S. Patent No. 8,377,919.

9. Attached hereto as Exhibit 8 is a true and correct copy of U.S. Patent No. 8,536,163.

10. Attached hereto as Exhibit 9 is a true and correct copy of U.S. Patent No. 8,716,271.

11. Attached hereto as Exhibit 10 is a true and correct copy of U.S. Patent No. 8,735,375.

12. Attached hereto as Exhibit 11 is a true and correct copy of an Office Action Response, dated January 17, 2008.

13. Attached hereto as Exhibit 12 is a true and correct copy of a Declaration Pursuant to 37 C.F.R. § 1.132, dated August 22, 2003.

14. Attached hereto as Exhibit 13 is a true and correct copy of Salah M.A.D. Zayed et al., "Dietary cancer risk from conditional cancerogens in produce of livestock fed on species of spruge (Euphorbiaceae) I. Skin irritant and tumor promoters of the ingenane diterpene ester type," *Cancer Res. Clin. Oncol*, 124: 131-140 (1998).

15. Attached hereto as Exhibit 14 is a true and correct copy of Evans, F.J. et al., "The Tiglane, Daphane and Ingenane Diterpenes, Their Chemistry, Distribution and Biological Activities, A Review." *Lloydia* 41(3): 193-233 (1978).

16. Attached hereto as Exhibit 15 is a true and correct copy of Evans, F.J. et al., "Pro-Inflammatory, Tumor-Promoting and Anti-Tumor Diterpenes of the Plant Families Euphorbiaceae and Thymelaeaceae." In: Hertz W., Grisebach H., Kirby G.W. (eds.), *Progress in the Chemistry of Organic Natural Products* 44:1-99 (1983).

17. Attached hereto as Exhibit 16 is a true and correct copy of Appendino, G., "Ingenane Diterpenoids." In: A.D. Kinghorn, H. Falk, S. Gibbons, J. Kobayashi (eds.), *Progress in the Chemistry of Organic Natural Products* 102:1-90 (2016).

18. Attached hereto as Exhibit 17 is a true and correct copy of an Office Action Response, dated October 25, 2001.

19. Attached hereto as Exhibit 18 is a true and correct copy of an Office Action Response, dated September 26, 2003.

20. Attached hereto as Exhibit 19 is a true and correct copy of a Final Rejection, dated August 29, 2003.

21. Attached hereto as Exhibit 20 is a true and correct copy of an Office Action Response, dated March 23, 2004.

22. Attached hereto as Exhibit 21 is a true and correct copy of excerpts from A Dictionary of Plant Sciences (2nd ed. 1988).

23. Attached hereto as Exhibit 22 is a true and correct copy of excerpts from the Academic Press Dictionary of Science and Technology (1992).

24. Attached hereto as Exhibit 23 is a true and correct copy of the Declaration of Dr. Peter Gordon Parsons under 37 C.F.R. § 1.132, dated October 24, 2001.

25. Attached hereto as Exhibit 24 is a true and correct copy of a Final Rejection, dated March 8, 2005.

26. Attached hereto as Exhibit 25 is a true and correct copy of an Amendment and Response to Final Office Action, dated January 10, 2012.

27. Attached hereto as Exhibit 26 is a true and correct copy of Ross, R.J. et al., "Ingenane Synthetic Studies. Stereocontrolled Introduction of All Oxygenated and Unsaturated Centers in an Ingenol Prototype." J. Am. Chem. Soc., 52:5497-5498 (1987).

28. Attached hereto as Exhibit 27 is a true and correct copy of Winkler, J.D. et al., "The First Total Synthesis of (\pm)-Saudin." J. Am. Chem. Soc., 124(33):9726-9728 (2002).

29. Attached hereto as Exhibit 28 is a true and correct copy of Arrhenius, G. et al., “Glycolonitrile Oligomerization: Structure of Isolated Oxazolines, Potential Heterocycles on the Early Earth.” J. Org. Chem., 62:5522-5525 (1997).

30. Attached hereto as Exhibit 29 is a true and correct copy of Fornies, J. et al., “Synthesis and Structural Characterization of the First Isolated Homoleptic Organoplatinum(IV) Compound: [Pt(C₆C₅)₄].” J. Am. Chem. Soc., 117:4295-4304 (1995).

31. Attached hereto as Exhibit 30 is a true and correct copy of Aitken, A., “The activation of protein kinase C by daphnane, ingenane and tiglane diterpenoid.” Bot J Linn Soc., 94:247-263 (1987).

32. Attached hereto as Exhibit 31 is a true and correct copy of a printout from Merriam-Webster.com, dated July 16, 2017.

33. Attached hereto as Exhibit 32 is a true and correct copy of Cross, S.E. et al., “Determination of the Effect of Lipophilicity on the *in vitro* Permeability and Tissue Reservoir Characteristics of Topically Applied Solutes in Human Skin Layers.” J. Invest. Dermatol., 120:759-764 (2003).

34. Attached hereto as Exhibit 33 is a true and correct copy of Cotran, R.S. et al., *Pathologic basis of disease* (5th ed. 1994).

35. Attached hereto as Exhibit 34 is a true and correct copy of Lalji, A. et al., “Actinic Keratosis and Squamous Cell Carcinoma.” Clinical Res Dermatol Open Access, 1(1):1-3 (2014).

36. Attached hereto as Exhibit 35 is a true and correct copy of U.S. Patent No. 7,141,237.

37. Attached hereto as Exhibit 36 is a true and correct copy of Dolan, J., "Column Diameter, Linear Velocity, and Column Efficiency." LCGC North America, 28(2):114-120 (2010).

38. Attached hereto as Exhibit 37 is a true and correct copy of Hong, D.D. et al., "Development and Validation of HPLC Stability-Indicating Assays." In: Carstensen, J., Rhodes, C.T. (eds.), *Drug Stability*. New York: Marcel Dekker, Inc. (3rd ed. 2000).

39. Attached hereto as Exhibit 38 is a true and correct copy of Yekkala, R. S. et. al., "Evaluation of an International Pharmacopoeia method for the analysis of nelfinavir mesilate by liquid chromatography." J Pharm Biomed Anal, 48(3):1050-1054 (2008).

40. Attached hereto as Exhibit 39 is a true and correct copy of Ukic, S. et al., "Optimization of IC Separation Based on Isocratic-to-Gradient Retention Modeling in Combination with Sequential Searching or Evolutionary Algorithm." Journal of Analytical Methods in Chemistry (2013).

41. Attached hereto as Exhibit 40 is a true and correct copy of excerpts from Sadek, P. C., *The HPLC Solvent Guide*. New York: John Wiley (2002).

42. Attached hereto as Exhibit 41 is a true and correct copy of Swartz, M., "HPLC Detectors: A Brief Review." Journal of Liquid Chromatography & Related Technologies, 33:1130-1150 (2010).

43. Attached hereto as Exhibit 42 is a true and correct copy of Dolan, J.W., "The Importance of Temperature." LCGC Europe (July 2002).

44. Attached hereto as Exhibit 43 is a true and correct copy of excerpts from the American Chemical Society, *Chemical Abstracts Vol. 15, No. 1* (1921).

45. Attached hereto as Exhibit 44 is a true and correct copy of excerpts from Tuzimski, T. et al., *High Performance Liquid Chromatography in Pesticide Residue Analysis*. Florida: CRC Press (2015).

46. Attached hereto as Exhibit 45 is a true and correct copy of excerpts from a Jenway Product Catalogue (2012).

47. Attached hereto as Exhibit 46 is a true and correct copy of the *Curriculum Vitae* of Mark S. Nestor, M.D., Ph.D.

48. Attached hereto as Exhibit 47 is a true and correct copy of the *Curriculum Vitae* of David R. Williams, Ph.D.

49. Attached hereto as Exhibit 48 is a true and correct copy of the *Curriculum Vitae* of Robert D. Voyksner, Ph.D.

50. I declare under penalty of perjury that the foregoing is true and correct.

Dated: July 20, 2017

By: /s/ Justin A. MacLean
Justin A. MacLean